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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,970	YIP ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) *18 and 24-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The Election filed on February 8, 2005 in response to the Restriction Requirement of November 17, 2004 has been entered. Applicants have elected Group I, claims 1-17 and 19-23 as specifically drawn to the special technical feature of a method for aiding a prostate cancer diagnosis.

Applicant's election with traverse of Group I, claims 1-17 and 19-23, has been acknowledged. The traversal is on the ground(s) that the prior art of Zetter et al., US Pat. No. 5, 858,681, does not disclose markers which are less than 27,000 daltons and that are differentially present in samples of a prostate cancer patient and a patient with benign hyperplasia. These arguments have been considered but are not found persuasive for the reasons set forth in the previous office action (11/17/04) and for the reasons set forth below.

When the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, only PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. In the instant case, the patent discloses (Table 1) that thymosin B15 (SEQ ID NO: 2) is differentially present in prostate carcinoma as compared to benign prostate hyperplasia. Zetter et al. further teaches that the amino acid sequence of SEQ ID NO: 2 consists of 45 amino acid residues which appears to have a molecular weight of less than 27,000 Da., i.e., 5304.10 Da (see attached from www.Scripps.edu/~cdputnam/protcalc.html). Thus, it is maintained that the technical feature linking the inventions of Groups 1-5 does not constitute a special technical feature as defined by PCT Rule 13.2 and does not define a contribution over the prior art.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-83 are currently pending in the application.

Claims 18 and 24-83 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 1-17 and 19-23 are currently under consideration.

Species Election

The Election of a Species filed on February 8, 2005 in response to the Restriction Requirement of November 17, 2004 has been entered. Applicant's elected seminal basic protein. However, Applicant's were required to elect one polypeptide having an apparent molecular weight from those listed in claims 2, 5, 39, 43, 51 and 55 which did not include seminal basic. Applicant's representative, Kenneth Weber, was contacted on 3/28/2005 by telephone to elect a species from claims 2 and 5. The election was made of a polypeptide having an apparent molecular weight of 5753 Da. Affirmation of this election must be made by applicant in replying to this Office action.

Information Disclosure Statement

The references cited in the Search Report filed on March 25, 2002 have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO/SB/08A and 08B form, must be filed within the set period for reply to this Office action.

Specification

The disclosure is objected to because of the following informalities: The specification of page 5 bridging page 6 appears to be missing a brief description of the drawling for Figure 2. In addition, the specification on page 33, line 20 uses the term "bound" to describe the presence of a polypeptide in a sample. It appears that bound should be changed to found. Applicants are reminded that no new matter should be introduced by amendment to the specification (see MPEP 35 USC 132).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps in claims 1 and 13 are: a correlation step describing how the results of the method relate back to the preamble of the method objectives.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 6-15, 17 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of markers, i.e., polypeptides, characterized by an apparent molecular weight of less than 27,000 Da or a genus of markers, i.e., polypeptides, generated by PSA-mediated proteolysis. However, the written description in this case only sets forth a representative number of species of peptide characterized by a molecular weight of less than 8714 Da, specifically those having a molecular weight of 2776, 2530, 2095, 3030, 3038, 3224, 3600, 3835, 3915, 3933, 4175, 4423, 4480, 5753, 6098, 6270, 6998, 7843, 8030, 8240 and 8714 Da and one species of peptide generated by PSA-mediated proteolysis of semenogelin I, seminal basic protein.

The specification teaches (page 2, line 33 to page 3, line 1) that specific markers of the invention include, but are not limited to, peptides which are present at elevated levels in samples from prostate cancer patients compared to samples from BPH patients. The specification further discloses (page 2, lines 30-33 and page 3, lines 10-11) that suitable markers include not only polypeptides having an apparent molecular weight of less than 27,000 Da, but also polypeptides

which are generated by PSA-mediated proteolysis such as the cleaved product generated by PSA-mediated proteolysis of semenogelin I. However, the written description (beginning on page 30, Examples) in this case only sets forth a representative number of species of peptide characterized by a molecular weight of less than 8714 Da, specifically those having a molecular weight of 2776, 2530, 2095, 3030, 3038, 3224, 3600, 3835, 3915, 3933, 4175, 4423, 4480, 5753, 6098, 6270, 6998, 7843, 8030, 8240 and 8714 Da and one species of polypeptide generated by PSA-mediated proteolysis of semenogelin I, seminal basic protein in association with differential expression; and therefore, is not commensurate with the full scope of any and/or all polypeptides having an apparent molecular weight of less than 27,000 Da or any and/or all polypeptides generated by PSA-mediated proteolysis. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of polypeptides that encompass the genus of markers having an apparent molecular weight of less than 27,000 Da which are differentially expressed nor does it provide a description of structural features that are common to the markers. Further, the specification fails to provide a representative number of polypeptides that encompass the genus of markers which are generated by PSA-mediated proteolysis along with a description of structural features that are common to the markers. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of markers, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Applicants should further refer to the revised interim Written Description Guidelines regarding protein variant language (see http://www.uspto.gov/web/menu/written.pdf).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only a peptide characterized by a molecular weight of less than 8714 Da, specifically those having a molecular weight of 2776, 2530, 2095, 3030, 3038, 3224, 3600, 3835, 3915, 3933, 4175, 4423, 4480, 5753, 6098, 6270, 6998, 7843, 8030, 8240 and 8714 Da and one species of peptide generated by PSA-mediated proteolysis of semenogelin I, seminal basic protein, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1-17 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of aiding a prostate cancer diagnosis comprising determining a test amount of a marker from blood, urine, serum, and tissue extracts, wherein the marker is a polypeptide which is differentially expressed in a prostate cancer patient and a benign prostate hyperplasia patient and has an apparent molecular weight of 5304.10 Da, does not reasonably provide enablement for a method of aiding a cancer diagnosis comprising determining a

test amount of a marker in any and/or all samples, wherein the marker is a polypeptide which is differentially expressed in a prostate cancer patient and a benign prostate hyperplasia patient and has an apparent molecular weight of less than 27,000 Da. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The instant claims read on method of aiding a cancer diagnosis comprising determining a test amount of a marker in any and/or all samples, wherein the marker is a polypeptide which is differentially expressed in a prostate cancer patient and a benign prostate hyperplasia patient and has an apparent molecular weight of less than 27,000 Da. Thus, the claims read on aiding a cancer diagnosis by determining in any sample any and/or all polypeptides which are differentially expressed in a prostate cancer patient and a benign prostate hyperplasia patient. Therefore, there must be a correlation between the sample and the polypeptides level in a patient suffering from prostate cancer vs. a patient suffering from benign prostate hyperplasia vs. a patient whom has no history of either of the two, i.e. control.

However, the scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art. The instant specification is not enabling for claims drawn to

aiding a cancer diagnosis by determining in any sample any and/or all polypeptides which are differentially expressed in a prostate cancer patient and a benign prostate hyperplasia patient. The specification teaches (page 6, lines 26-34) that a marker in the context of the present invention refers to a polypeptide which is differentially present in a sample taken from a patient having prostate cancer as compared to a comparable sample taken from a subject who does not have prostate cancer (e.g. benign prostate hyperplasia patients or healthy subjects). For example, the specification discloses (beginning on page 30 to page 34, line 25) a number of polypeptides which where shown to be present in seminal plasma samples from patients with prostate cancer as compared to patients with BPH (benign prostate hyperplasia). Conversely, the specification appears to be silent on the presence of the polypeptides in samples taken from healthy patients. Thus, one cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to aiding prostate cancer diagnosis comprising detecting a polypeptide which is differentially expressed in a prostate cancer patient and a benign prostate hyperplasia patient, and applicant has not enabled the differential level of the polypeptide as a diagnostic for prostate cancer because it has not been shown that these levels are not present to some extent in healthy individuals.

For example, if the marker were a polypeptide generated by PSA-mediated proteolysis of semenogelin I, such as seminal basic, those of skill in the art would recognize the unpredictability of diagnosing a prostate cancer patient based on the differentiated level of the protein fragments in seminal fluid. For example, Lilja et al. (J. Bio. Chem. 1989; 264: 1894-1900) discloses semenogelin as a predominant protein in human semen. Specifically, the reference teaches that liquefaction of the seminal gel parallels proteomic fragmentation of semenogelin which is mainly due to the proteolytic activity of the prostate specific antigen (page 1894, 2nd column, 2nd paragraph). Moreover, Malm et al. (The Prostate 2000; 45: 132-139) examined the enzymatic action of prostate specific antigen and substrate specificity to semenogelin in semen (abstract). The reference teaches (page 133, 1st column, 1st paragraph) that in semen approximately two thirds of PSA remains enzymatically active, i.e., proteolysis of semenogelin, while the remaining 30% to 40% is inactive mainly due to internal cleavage and complexed PSA contributing only a small percent. In contrast, Malm et al. disclose (page 133, 1st column, 1st paragraph) that in serum and blood PSA mainly occurs as a complex and clinically, these different forms are used to enhance the discrimination of men with benign prostate hyperplasia and prostate adenocarcinoma. Thus, one of skill in the art would

recognize the need for a control because they would expect a polypeptide generated by PSA-mediated proteolysis of semenogelin I to be found in seminal fluid/semen of healthy individuals.

A review of the literature pertaining to prostate cancer diagnosis emphasizes the use of controls. Thus, if the determining step was based on proteomics, those of skill in the art would recognize the unpredictability of diagnosing a disease without a control. For example, Adam et al. (Cancer Research 2002; 62: 3609-3614) used proteomic profiling for detecting prostate cancer. Specifically, the reference teaches (page 3613, 1st column, 1st paragraph) that their successful development of a diagnostic system was achieved by using a large, carefully chosen training set of randomly selected samples and also, disclose the difficulties in selecting a cancer free control population because "healthy" men with normal PSA and normal DRE rarely undergo a prostate biopsy to be certain that the controls are truly negative. Adam et al. further teach (page 3613, 1st column, 2nd paragraph) that a "normalization" process is critical because most all of the protein alterations between cancer and non cancer cohorts are based on overexpression or under expression of proteins and not solely on their presence or absence. Furthermore, Paweletz et al. (Proc. Amer. Assoc. Cancer Research 1999; 40: 411) teach a novel, proteomic approach to monitor carcinogenic disease progression from cancer tissues. In the report, the authors found a highly reproducible protein fingerprint for three different cancers which defined protein expression changes from normal epithelium to pre-invasive carcinoma cells to actual invasive carcinoma in a cell-type and metastatic-specific manner. Thus, in view of the teachings above and the lack of guidance, workable examples and or exemplification in the specification, it would require undue experimentation by one of skill in the art to determine with any predictability, that the method would function as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an

> application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Zetter et al. (US 5,858,681, 1996).

Zetter *et al.* disclose a method of diagnosing prostate cancer in a patient comprising determining the level of a polypeptide in a biological specimen, wherein the level of the polypeptide in the sample greater than the base line is indicative of cancer (column 2, lines 60-64). With regards to the biological specimen, the patent teaches (column 2, lines 64-67) that the biological specimen includes, for example, blood, tissue, serum and urine. With regards to the polypeptide, Zetter et al. teach that the polypeptide is an amino acid sequence set forth in SEQ ID NO: 2 referred to as "thymosin B15" which is differentially present in prostate carcinoma compared to benign prostate hyperplasia as detected by an immunoassay (column 12, Table 1). The reference further discloses (columns 13 and 14, sequence listing) that the amino acid sequence set forth in SEQ ID NO: 2 consists of 45 amino acids which has an apparent molecular weight of less than 27,000 Da. (see attached from www.Scripps.edu/~cdputnam/protcalc.html, 5304.10 Da).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zetter et al. (US 5,858,681, 1996) in view of Hutchens (WO 98/59360, 1998).

Zetter et al teach, as applied to claims 1, 6, 8 and 10 above, a method of diagnosing prostate cancer in a patient by determining the level of a polypeptide in a biological specimen such as serum or urine, wherein the level of the polypeptide is differentially present in samples of a prostate cancer patient and a benign prostate hyperplasia patient. Moreover, the patent teaches that the polypeptide is less than 27,000 Da.

Zetter et al. does not teach that a method of determining a test amount of a plurality of markers from a sample (claim 7). Nor does the patent teach that the determining step was carried out via laser desorption mass spectrometry (claims 11-12).

Hutchens et al. teach a method of absorbing analytes to a substrate under a plurality of different selectivity conditions, and detecting the analytes retained on the substrate by desorption spectrometry (abstract). Specifically, the reference teaches (page 34, lines 21+) that desorption spectroscopy includes, but is not limited to surface-enhanced laser desorption/ionization (SELDI).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the "technology" of laser desorption mass spectrometry for determining protein expression in a prostate cancer patient. One would have been motivated to do so because as evidenced by Hutchens et al., the process for identifying a potential marker for a disease state has been difficult due to a long and tedious process of identification of a polypeptide, followed by production of an antibody (page 3, lines 5-21). Thus, one of ordinary skill in the art would have a reasonable expectation of success that by detecting the peptide taught by Zetter et al. using laser desorption mass spectrometry in view of Hutchens et al., one would achieve a fast and reliable method of diagnosing prostate cancer in a patient by measuring a single marker or a plurality or markers.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 6-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/221,905.

Although the conflicting claims are not identical, they are not patentably distinct from each other because a species anticipates a genus. In the instant case, the specific protein markers having a molecular weight of 97402.68, 9752.30, 8766.93, 6277.97, or 2781.72 Da, claimed in the conflicting applications appears to fall within the same scope as the genus of a markers having an apparent molecular weight of less than 27,000 da claimed in the application being examined and, therefore, a patent to the genus of a markers having an apparent molecular weight of less than 27,000 Da would necessarily, extend the rights of a specific marker should the application being examined issue as a patent after the conflicting application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Therefore, NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
9/17/05